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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

October 27, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Colleen Freeman
Chief of Radiology
Fort McPherson Army Health Clinic
Usahc Radiology Department
Fort McPherson, GA 30330-5000

WARNING LETTER

Dear Ms. Freeman:

Your facility was inspected on September 18, 1997 by Investigator Stephanie Harrell of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Radiologic technologist's certification: [redacted]

Radiologic technologist's documentation of training: [redacted]

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirement, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

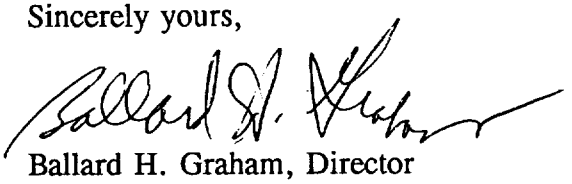
If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

U.S. Food and Drug Administration
Compliance Enforcement
60 8th Street, N.E.
Atlanta, Georgia 30309

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call John J. McCall at (404) 347-3162.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District